

K042712
172

OCT 15 2004

510(k) Summary

Special 510(k) summary of safety and effectiveness

Company information

Safety Syringes, Inc.
1925 Palomar Oaks Way, Suite 204
Carlsbad, CA 92008 USA

Device Identification

Trade Name – UltraSafe Passive™, X-Series, Needle Guard – Models X50, X100, X100L, X150, X225, X300, X500
Classification Name – Syringe, Piston (accessory)
Classification – Class II
Product Code – 80 FMF

Predicate Device

The UltraSafe® Injection System Needle Guard – Models B50, B100, B100L, B150, B225, and B300

Device Description

The UltraSafe Passive™, X-Series, Needle Guard is an accessory for ISO Standard pre-filled glass syringes. ISO Standard pre-filled glass syringes are supplied in multiple sizes. They fit with ISO Standard pre-filled glass syringes ranging from 0.5 mL to 5.0 mL of fill volume.

The guards are designed to meet the requirements specified in ISO 11040-4 Pre-filled syringes – Part 4 Glass barrels for injectables (March 1995).

Intended Use

The UltraSafe Passive™, X-Series, Needle Guard is intended for use as a safety mechanism designed to reduce the occurrence of accidental needlesticks to healthcare professionals during disposal of a used syringe and needle assembly. The UltraSafe Passive, X-Series, Needle Guard is snapped onto the barrel of an ISO Standard pre-filled glass syringe, in a retracted position. Upon completing the injection, the UltraSafe Passive, X-Series, Needle Guard passively activates and covers the exposed needle. When the Passive Needle Guard is activated, it provides protection from an accidental needlestick. The healthcare professional disposes the used syringe and needle assembly in a sharps container.

The intended patient population is unrestricted and includes children and adults.

K042712
282

The intended environment of use is where healthcare professionals are required to administer medication, including vaccines, by means of a syringe.

Indications for Use

UltraSafe Passive™, X-Series, Needle Guards are single use devices that are indicated for use as an accessory with ISO Standard pre-filled glass syringes to protect healthcare professionals from accidental needle sticks.

This device is used on a wide range of patients, including children and adults, and parenteral methods of administration.

Comparison of the UltraSafe® Injection System Needle Guard – B-Series to the UltraSafe Passive™, X-Series, Needle Guard

The UltraSafe Passive™, X-Series, Needle Guards are modifications of the previously cleared ~~(K082070)~~ UltraSafe Injection System Needle Guard, B-Series. The B-Series are manually activated needle guards. The X-Series are passively (automatically) activated needle guards.

The basic design, function, intended use, and indications for use of the B-Series and X-Series are similar.

Safety Syringes, Inc. conducted iterative user evaluations of the X-Series needle guard. A controlled simulated clinical use test was conducted with the UltraSafe Passive, X-Series, Needle Guard to validate the product in the hands of typical users. The UltraSafe Injection System Needle Guard, B-Series, was used as the control.

In the controlled simulated clinical use test, each of the specified acceptance criteria were either met or exceeded. The nurses involved in this study rated the X-Series to be equal to, or better than, the B-Series on all of the parameters related to safety, performance, and usability.

In addition to evaluating safety, performance, and usability parameters, there were questions of the study participants regarding the clarity and adequacy of the written and illustrated Directions for Use, and the participants' response to the need for in-service training. On each of the parameters, the X-Series rated as equal to, or better, than the B-Series.

* K972878 Thomas L. Hall 10/27/04



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 15 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Thomas L. Hall
Director, Regulatory Affairs and Quality Assurance
Safety Syringes, Incorporated
1939 Palomar Oaks Way, Suite A,
Carlsbad, California 92009

Re: K042712
Trade/Device Name: Tamper Evident UltraSafe® Passive™ Delivery System
Syringe, Piston (Accessory)
Regulation Number: 880.5860
Regulation Name: Antistick Syringe, Piston Syringe
Regulatory Class: II
Product Code: MEG, FMF
Dated: September 27, 2004
Received: September 30, 2004

Dear Mr. Hall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

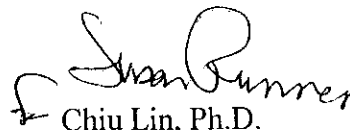
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042712

Indications for Use Statement

510(k) Number: _____

Device Name: Tamper Evident
UltraSafe® Passive™ Delivery System
Syringe, Piston (Accessory)

Indications for Use:

Single Use devices that are indicated for use as an accessory with pre-filled ISO Standard glass syringes to aid in the protection of healthcare professionals from accidental needlesticks.

These devices can be used on a wide range of patients, including children and adults, and parenteral methods of administration.

Shane Neveaux for ADW
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

10/14/04

510(k) Number: K042712

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X
(Per 21 CFR 801.109)

OR

Over the Counter _____